STANDARD IMAGING

K082773

NOV 19 2008

September 17, 2008

Subject:	510(k) Summary of Safety and Effectiveness Information for the Standard Imaging IMSure Brachy QA Software	
Proprietary Name:	Standard Imaging IMSure Brachy QA Software	
Common Name:	Dose Validation Software	
Classification Name:	Primary:	Medical Charged-Particle Radiation Therapy System (accessory to)
	Secondary:	Remote Controlled Radionuclide Applicator System (accessory to) Radionuclide Brachytherapy Source (accessory to)
Classification:	Primary:	Class II – 21CFR892.5050 – LHN, IYE
	Secondary:	Class II – 21CFR892.5700 – JAQ Class II – 21CFR892.5730 – KXK
Panel:	Radiology	
Predicate Devices:	Primary:	Standard Imaging (Prodigm), IMSure QA Software 510(k) Number K031975
	Secondary:	Oncology Data Systems, MU Check v7.0 (Brachy Check) 510(k) Number K061152
Contact Person:	Raymond Riddle, PE, RAC Chief Regulatory Officer	

The 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 1992.

The Standard Imaging IMSure Brachy QA Software was designed to comply with the applicable portions of the following voluntary standard:

- IEC 60601-1-4 (Edition 1.1 2000-04) – Collateral standard for programmable medical systems

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IMSure Brachy QA Software is a stand alone software application product intended for use as a quality assurance tool to verify brachytherapy treatment plans developed on a radiation therapy treatment planning system with the appropriate transfer format. It may also be used as a segregated standalone application in the IMSure QA Software suite of software products.

This product is intended for use by trained medical physicists, physicians, or dosimetrists. The calculation results must be evaluated by qualified personnel before a patient treatment. It is the responsibility of the medical physicist, physician or dosimetrist to determine whether the dosimetric accuracy is adequate for a particular patient.

Dose modeling of a source is based on the AAPM TG-43 formalism, and may be adjusted by a qualified user to match measured or published results. IMSure Brachy QA Software does not control any radiation delivery devices and does not allow the export of calculated information.

The Standard Imaging IMSure Brachy QA Software has been verified and validated at Standard Imaging, and addressed the following functional areas:

- Installation
- Import Tool Module
- User Preferences Module
- QA Module
- Source Library Module
- User Management Module
- Simple 1 strand +xyz to –xyz
- Dual IR-192 dwl
- 24 channels
- Xoft
- 4 I125 point
- Line 1D aniso
- Line scalar aniso

Additionally, the IMSure Brachy QA Software was successfully evaluated by the following beta sites:

- UCSD Hospital, San Diego, CA
- Grant Methodist Hospital, Columbus OH
- Memorial Hospital, South Bend, IN
- Edward Hospital, Naperville, IL
- Texas Oncology Hospital, Klabzuba, TX

The Standard Imaging IMSure Brachy QA Software has met its predetermined design specifications, risk analysis and validation objectives.

STANDARD IMAGING, INC. 3120 Deming Way, Middleton, WI 53562-1461 800-261-4446 608-831-0025 PH 608-831-2202 FAX www.standardimaging.com

General Information

Device Name – Proprietary:

IMSure Brachy QA Software - During development, the name has evolved, resulting in many of the documents in this 510(k) having slightly different names. Upon 510(k) clearance, all documents, including manuals, advertisements, labeling and software supplied to the marketplace and/or users will use the name IMSure Brachy QA Software.

Device Name – Common:

Dose Validation Software

Device Name – Classification(s):

Primary:	Medical Charged-Particle Radiation Therapy System (accessory to)
Secondary:	Remote Controlled Radionuclide Applicator System (accessory to)
	Radionuclide Brachytherapy Source (accessory to)

Device Panel:

Radiology

Device Classification(s):

Primary:	Class II – 21CFR892.5050 – LHN, IYE
Secondary:	Class II – 21CFR892.5700 – JAQ, Class II – 21CFR892.5730 – KXK

Predicate Devices:

Primary:	Standard Imaging (Prodigm), IMSure QA Software
	510(k) Number K031975
Secondary:	Oncology Data Systems, MU Check v7.0 (Brachy Check)
	510(k) Number K061152

Performance Standards:

To the best of Standard Imaging's knowledge, performance standards have not been promulgated by FDA for this device.

Establishment Registration Number:

2184007

Owner/Operator Number:

9003193

Facility Information:

Standard Imaging, Inc.
3120 Deming Way
Middleton, WI 53562

Telephone:	(608) 831-0025
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Webpage:	www.standardimaging.com

Device Background

Standard Imaging acquired the IMSure QA Software from Prodigm, Inc. in 2005. Since that time the company has made minor incremental improvements to the product. Since Standard Imaging had a strong market presence with brachytherapy quality assurance products, a simple standalone software product in the IMSure mold was an obvious development choice.

Device Description

IMSure Brachy QA Software is a stand alone software application product intended for use as a quality assurance tool to verify brachytherapy treatment plans developed on a radiation therapy treatment planning system with the appropriate transfer format. It may also be used as a segregated standalone application in the IMSure QA Software suite of software products.

This product is intended for use by trained medical physicists, physicians, or dosimetrists. The calculation results must be evaluated by qualified personnel before a patient treatment. It is the responsibility of the medical physicist, physician or dosimetrist to determine whether the dosimetric accuracy is adequate for a particular patient.

IMSure Brachy QA Software independently computes a modeled dose that would be delivered by a high dose rate (HDR) or low dose (LDR) brachytherapy system to a patient and compares it to the dose predicted by a primary treatment planning system. IMSure Brachy QA Software imports a file produced by a primary HDR or LDR treatment planning system (TPS), in the format of an industry standard Dicom-RT™ or vendor specific file, which contains information about a treatment. The files contain information about applicators or catheters and the associated source information in each catheter, such as source type, source strength, source location and source duration. The files may also contain information about specific calculation points and the dose predicted by the primary planning system, as well as patient specific information. The dose computation algorithm used is a superposition of point or line sources, incorporating 3-D geometrical features of the source construction, as well as radiological features of the source composition. Dose modeling of a source is based on the AAPM TG-43 formalism, and may be adjusted by a qualified user to match measured or published results.

After importing a TPS plan, a user may edit the information, adding or modifying source positions, durations (or dwell times), type, or activity strength. Calculation point information may be edited as well. A 3-D view of the applicators, source positions, and calculation point positions is provided. A paper or electronic record can be stored including the final dose computation for each calculation point compared to the dose computed by the TPS, as well as relevant patient information for long term documentation. IMSure Brachy QA Software does not control any radiation delivery devices and does not allow the export of calculated information.

IMSure Brachy QA Software is provided to the customer on a CD. It requires the Microsoft Windows Operating System 2000 with service pack 2 or better, or XP. Computer system requirements include Pentium III or equivalent, a minimum of 256 MB RAM and 100 MB available hard drive space. Display requirements include 1024 x 768 minimum resolution and an OpenGL compatible video card meeting OpenGL 1.1 specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Raymond T. Riddle, PE, RAC
Chief Regulatory Officer
Standard Imaging, Inc.
3120 Deming Way
MIDDLETON WI 53562-1461

NOV 19 2008

Re: K082773
Trade/Device Name: IMSure Brachy QA Software
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: September 18, 2008
Received: September 22, 2008

Dear Mr. Riddle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082773

Device Name: IMSure Brachy QA Software

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Prescription Use __X__ (Part 21 CFR 801 Subpart D) and/or Over-the-Counter-Use _____ (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K082773